



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 29 2005

Young Ho Choi
Access Bio, Inc.
2033 Route 130, Unit H
Monmouth Junction, NJ 08852

Re: k051925
Trade/Device Name: CareStart Cardiac 3-in-1 Troponin I/CK-MB/Myoglobin Test
CareStart Cardiac 2-in-1 Troponin I/Myoglobin Test
CareStart Cardiac Troponin I
CareStart Cardiac CK-MB
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI, JHT, DDR
Dated: October 24, 2005
Received: October 26, 2005

Dear Mr. Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

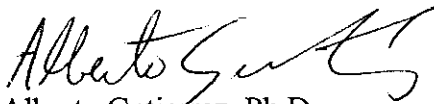
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alberto Gutierrez", with a stylized flourish at the end.

Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k051925

Device Name: CareStart™ Cardiac 3-in-1 Troponin I/CK-MB/Myoglobin Test

Indications For Use:

CareStart™ Cardiac 3-in-1 Troponin I/CK-MB/Myoglobin Test is intended for the qualitative detection of cardiac troponin I, CK-MB and myoglobin in human blood, serum or plasma. Measurement of cardiac troponin I, CK-MB and myoglobin aids in rapid diagnosis of acute myocardial infarction. The performance characteristics of the test have not been evaluated in a point-of-care (POC) setting.

Prescription Use X
(Part 21 CFR 801 Subpart D)

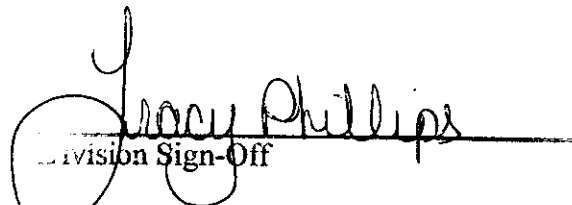
AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K051925

Indications for Use

510(k) Number (if known): k051925

Device Name: CareStart™ Cardiac 2-in-1 Troponin I/Myoglobin Test

Indications For Use:

CareStart™ Cardiac 2-in-1 Troponin I/Myoglobin Test is intended for the qualitative detection of cardiac troponin I, and myoglobin in human blood, serum or plasma. Measurement of cardiac troponin I, and myoglobin aids in rapid diagnosis of acute myocardial infarction. The performance characteristics of the test have not been evaluated in a point-of-care (POC) setting.

Prescription Use X
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
10/30/2010 K051925

Indications for Use

510(k) Number (if known): k051925

Device Name: CareStart™ Cardiac CKMB Test

Indications For Use:

CareStart™ Cardiac CKMB Test is intended for the qualitative detection of CK-MB in human blood, serum or plasma. Measurement of CK-MB aids in rapid diagnosis of acute myocardial infarction. The performance characteristics of the test have not been evaluated in a point-of-care (POC) setting.

Prescription Use X
(Part 21 CFR 801 Subpart D)

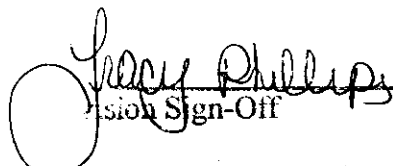
AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Page 1 of 1


Tracy Phillips
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K051925

Indications for Use

510(k) Number (if known): k051925

Device Name: CareStart™ Cardiac Troponin I Test

Indications For Use:

CareStart™ Cardiac Troponin I Test is intended for the qualitative detection of cardiac troponin I in human blood, serum or plasma. Measurement of cardiac troponin I aids in rapid diagnosis of acute myocardial infarction. The performance characteristics of the test have not been evaluated in a point-of-care (POC) setting.

Prescription Use X
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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Jacey Phillips
Special Agent in Charge

Office of In Vitro Diagnostic Device
Evaluation and Safety

 K051925